

### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

July 29, 2022

Charles Levey
NA Regulatory Lead
Bayer Environmental Science
5000 Centregreen Way, Suite 400
Cary, NC 27513, USA

Subject: Label Amendment – Added label language related to Butoxypolypropylene

Glycol Interim Registration Review Decision (Case # 3123) dated February 2021

Product Name: Stabilene Fly Repellent Insecticide

EPA Registration Number: 432-978

Application Date: 07/13/2020, 06/08/2021

Decision Number: 569722, 584594

Dear Mr. Levey:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. The next label printing of this product must use this labeling unless subsequent changes have been approved. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

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The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the Registration Review of the above referenced product in connection with the Butoxypolypropylene Glycol Interim Registration Review Decision, and has concluded that your submission is acceptable.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact Robert Mitchell at 202-566-2842 or via email at <a href="mailto:mitchell.robert@epa.gov">mitchell.robert@epa.gov</a>.

Sincerely,

Elizabeth Fertich Product Manager 4

Invertebrate-Vertebrate Branch 1

Registration Division

Office of Pesticide Programs

Enclosure

# STABILENE® FLY REPELLENT INSECTICIDE

ACCEPTED

07/29/2022

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

432-978

FOR FORMULATION INTO INSECTICIDES LABELED FOR DIRECT APPLICATION (I.E., DIRECT SPRAYS AND WIPE-ON PRODUCTS) TO HORSES, EITHER INDOORS OR OUTDOORS IN CLOSE PROXIMITY TO THE STABLE, OR TO INDOOR PREMISES (STABLES).

DO NOT USE STABILENE IN THE FORMULATION OF PRODUCTS INTENDED FOR USE ON MEAT OR DAIRY ANIMALS, POULTRY, OR IN FARM STRUCTURES OR BUILDINGS HOUSING FOOD PRODUCING ANIMALS OR POULTRY, OR IN MILK ROOMS

**ACTIVE INGREDIENT:** 

EPA Reg. NO. 432-978

EPA Est. No.

# KEEP OUT OF REACH OF CHILDREN CAUTION

See [Back][Side] Panel for First Aid Instructions and [Leaflet][Booklet] for Complete Precautionary Statements and Directions for Use. (Note to reviewer: Location of additional precautionary statements, directions for use will vary between those listed, depending on container type/size.)

For MEDICAL and TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577 (or specific company number)

For PRODUCT USE Information Call 1-800-331-2867 (or specific company number)

FIRST AID	
If on skin or clothing:	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a Poison Control Center or doctor immediately for treatment advice.</li> </ul>
If in eyes:	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a Poison Control Center or doctor immediately for treatment advice.</li> </ul>
If swallowed:	<ul> <li>Call a Poison Control Center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
Have the product container	HOT LINE NUMBER [PYRETHROID] or label with you when calling a poison control center or doctor, or going for treatment. You may

#### PRECAUTIONARY STATEMENTS

also contact 1-800-334-7577 for emergency medical treatment information.

## HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. When using this product, wear a long –sleeved shirt, long pants, socks, shoes, and rubber gloves. Wash thoroughly with soap and water after handling this product and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

#### **ENVIRONMENTAL HAZARDS**

This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA. Do not contaminate water by cleaning of equipment or disposal of wastes.

#### **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

This product is intended for formulation use only. The formulator using this concentrate is responsible for obtaining EPA registration for his formulated product. This product may be used to formulate products for specific uses not listed on this label if the formulator has complied with the U.S. EPA submission requirements regarding support of such uses.

Only for formulation into an insecticide for the following uses:

- For spray application, use only for direct application to horses, indoors or in close proximity to the stable, or to indoor premises (stables).
- (2) For non-spray application (as a wipe-on), use only for direct application to horses indoors or in close proximity to the stable.
- (3) Not for use in formulating products for outdoor misting application.
- (4) Not for use on horses under six weeks of age or those intended for slaughter.

#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

**Pesticide Storage:** Keep container closed when not in use. Do not store near food or feed. Protect from freezing. In case of spill or leak on floor or paved surfaces, soak up with sand, earth, or synthetic absorbent. Remove to chemical waste area. In case of spill or leakage, soak up with an absorbent material such as sand, sawdust, earth, fuller's earth, etc. Dispose of pesticide and absorbents with chemical waste.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of at an approved waste disposal facility.

#### **Container Handling:**

For Non-Refillable Containers:

Non-refillable container. Do not reuse or refill this container. Triple rinse as follows: Empty the remaining contents into mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into mix tank or store rinsate for later disposal. Repeat this procedure two more times. Offer for recycling, if available or dispose of empty container in a sanitary landfill or, if allowed by government regulations, by burning or incineration. If container is burned, stay out of smoke. Consult Federal, State, or Local disposal authorities for approved alternative procedures.

For Refillable Containers:

Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into rinsate collection system. Repeat this rinsing procedure two more times. Offer for recycling, if available or dispose of empty container in a sanitary landfill or, if allowed by government regulations, by burning or incineration. If container is burned, stay out of smoke. Consult Federal, State, or Local disposal authorities for approved alternative procedures.

#### DISCLAIMER AND INDEMNITY FOR FORMULATORS' USES

TO THE EXTENT ALLOWED BY APPLICABLE LAW, THE MANUFACTURER EXPRESSLY DISCLAIMS ALL LIABILITY FOR CLAIMS AND ACTIONS (WHETHER BASED ON CONTRACT, TORT, STRICT LIABILITY OR BREACH OF WARRANTY) ARISING OUT OF, RESULTING FROM OR CONNECTED WITH A FORMULATION CONTAINING THIS PRODUCT WHEN USED FOR ANY PURPOSE OTHER THAN THOSE USES SET FORTH IN SECTION(S) [(1) – (5)] OF THE DIRECTIONS FOR USE. THE MANUFACTURER HAS NOT DEVELOPED SCIENTIFIC DATA TO SUPPORT, NOR HAS IT EXPLICITLY OR IMPLICITLY APPROVED, ANY USES OTHER THAN THOSE IN [(1) – (3)] OF THE DIRECTIONS FOR USE.

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THIS DISCLAIMER AND INDEMNITY IS IN ADDITION TO, NOT IN LIEU OF, THE BELOW DISCLAIMER AND LIMITATIONS.

#### IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

**CONDITIONS:** The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience LP. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE LP MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience LP is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE LP DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

**LIMITATIONS OF LIABILITY:** TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE LP"S ELECTION, THE REPLACEMENT OF PRODUCT.

**Net Content:** 

#### PRODUCED FOR



Bayer Environmental Science A Division of Bayer CropScience LP 5000 CentreGreen Way, Suite 400 Cary, NC 27513

Stabilene Fly Repellent Insecticide (PENDING) 04/15/2019, 04/17/2019, 06/17/2019, 07/01/2020, 07/07/2020, 07/08/2020, 08/31/2020, 07/06/2022